REMARKS

Reconsideration is respectfully solicited.

Applicants respectfully traverse the rejections of all claims under 35 U.S.C. 102 and of specified claims under 35 U.S.C 112, first and second paragraphs.

Applicants respectfully traverse the U.S. Patent & Trademark Office [hereinafter "PTO"] rejections of the claims 40, 42-57, 59-60, and 62-63 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Applicants rely on MPEP [the Manual of Patent Examiner Procedure] Section 2163.04, which requires the Examiner to make factual findings and admonishes against general conclusory allegations.

Applicants submit that no fact finding has been made with a view to the content of the application.

The Section 112, first paragraph, rejections of claims 42, 43, 47, 54, 49, 50, 56, and 57, which will be discussed first, are different in reasoning from the rejections of claims 44 and 51. The PTO alleges:

> **"Regarding claim 40, the limitation that the acrylamide, N,N-dimethylacrylamide,** or mixtures thereof serve as a tie coat to adhere an ...
> "Regarding claim 42, the limitation that the acrylamide, N,N-dimethylacrylamide, or mixtures thereof comprise functional groups to attach or bind physiologically or pharmacologically active agents is not described...
> "Regarding claim 43, the limitation that the acrylamide, N,N-dimethylacrylamide, or mixtures thereof comprise a drug depot permitting the delivery of drugs from the graft polymer coating is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. ..
>
> ***"Regarding claims 47 and 54, the limitation that the monomers selected from the*** Markush group of possible monomers for the coating layer serve as a tie coat to adhere an additional layer to the substrate is not described in the specification in such a way as to reasonably convey to one skilled in the art that

the inventor, at the time the application was filed, had possession of the claimed invention.. .

"Regarding claims 49 and 56, the limitation that the monomers selected from the Markush group of possible monomers for the coating layer comprise functional groups to attach or bind physiologically or pharmacologically active agents is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. The specification teaches broadly that graft polymerized coating monomers can be chosen that comprise functional groups to attach or bind physiologically or pharmacologically active agents, but does not teach that any of the particular monomers of the Markush groups of claims 47 and 54 are used for this purpose...

"Regarding claims 50 and 57, the limitation that the monomers selected from the Markush group of possible monomers for the coating layer comprise a drug depot permitting the delivery of drugs from the graft polymer coating is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. The specification teaches broadly that graft polymerized coating monomers can be chosen that comprise a drug depot permitting the delivery of drugs from the graft polymer coating, but does not teach that any of the particular monomers of the Markush groups of claims 47 and 54 are used for this purpose." [Office Action, page 2-page 6]"

The PTO finds that the express description ***of the functions of those graft polymers or copolymers,*** [e.g. as a tie coat or a drug depot] reported at page 8 of the specification, does not apply to species of the graft polymers or copolymers (in specifically rejected claims) but only applies to the phrase 'graft polymer/copolymer,' ***generically***. A genus is constituted by the species which it defines. Logically, if the generic group is categorized as being capable of satisfying a function then member(s) of that generic group satisfy the function, absent evidence to the contrary. There is no evidence to the contrary in the record. The PTO has not carried the burden of proof which it bears. MPEP Section 2163.04 [relying on ***In re Wertheim.***]

Applicants submit that no fact finding has been made with a view to the content of the application with respect to the rejections of claims 42, 43, 47, 54, 49, 50, 56, and 57. For example, in the rejections the PTO fails to read the specification at page 8, at page 17 and the Examples at pages 22-27, and the originally filed claims. In applicants' view, the specification as filed shows a constructive reduction to practice of the claims originally filed and a constructive reduction to practice of the claims under examination and that applicants were in possession of both sets of claims.

The USPTO reasons for rejection of Claims 44 and 51 are different:

> "Regarding claims 44 and 51, the specification does not teach that the graft polymerized coating is formed of pyridine or piperidene. The specification teaches some specific monomers such as 2- or 4-vinylpyridine, 4- or 2-methyl-5-vinylpyridine, and N-methyl-4-vinylpiperidine, but does not teach that any pyridine or piperidene may be used to form the coating as claimed in claims 44 and 51." [August 2006 Office Action, page 4.]

The claims instead recite in pertinent part,

> substrate, forming a coating thereon, wherein said coating on said substrate is a polymer or copolymer or a derivative of said polymer or copolymer formed from a monomer or derivative thereof selected from the group consisting an acrylamide, N,N-dimethylacrylamide, polyethyleneglycolacrylate, alkylacrylate, pyridine, piperidene, maleic acid, hydroxyethyl methacrylate, and admixtures thereof.
>
> polymer or copolymer formed from a monomer or derivative thereof selected from the group consisting an acrylamide, N,N-dimethylacrylamide, polyethyleneglycolacrylate, alkylacrylate, pyridine, piperidene, maleic acid, hydroxyethyl methacrylate, and admixtures thereof.

Specifically, the USPTO error is in a reconstruction of claim terminology.

Applicants respectfully traverse the rejection of Claims 44-57, 59-60, and 62-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The phrase "selected from the group" is added between "copolymers" and "of". It is believed that the rejection is now moot. Claim 55 and amended Claim 44 herein parallel each other in terminology and the USPTO Examiner's interpretation for the purposes of search.

Applicants respectfully traverse the rejections under 35 USC 102, over Michal [US 6287285] and request reconsideration. Applicants rely on the MPEP Section 2131, which indicates that a reference, asserted by the U.S. PTO as an anticipatory reference, must describe each and every element of the claim under examination. In applicants' view, Michal [US 6287285] does not satisfy those requirements of Section 2131. The discussion immediately below deals with the Michal rejection of Claims 37, 44 and 51, the independent claims of the application. As a matter of law, if the reference does not anticipate claims 37, 44 and 51, the same reference can not anticipate dependent claims properly dependent from claims 37, 44 and 51, cf. 35 U.S.C. 112, second paragraph, last sentence.

Michal describes a coated medical device. The device itself is described at column 5 lines 33 et seq. to be of conventional material or a metal device. The reference further states that the device may be formed of HDPE, PET, polyolephinic ionomers, nylon and the like [column 5 lines 35-41].

Different sets of embodiments are described in Figures 1-4 [column 2] as opposed to embodiments in Figures 5, [column 11] and Figure 8 and 10-12. In the embodiment of Figures 1-4, a device-support is coated with a first coating material of vinyl , acrylate, and allyl such as any oligomer or monomer, e.g. divinyl benzene, n-vinyl pyrrolidone, and triethylene glycol divinyl ether. The following are exemplary of the acrylate: trimethylol propane triacrylate,

pentaerythrito tetra-acrylate, and Bisphenol A ethoxylate diacrylate; the following are exemplary of the allyl :allyl ether, di-allyl maleate, and tri-allyl isocyanurate. Please see Michal Column 6 lines 55 et seq.

The error in the PTO reasoning is two-fold. To attempt to satisfy the MPEP requirement that an anticipatory reference must provide description of each and every element of the claim under examination, the PTO must eliminate recitations from the rejected claims and disregard express description in Michal et al. The PTO states,

> Regarding claim 37, Michal et al anticipate a medical device comprising a substrate constructed and arranged for insertion into a patient and having at least one lumen, said substrate having an exterior surface and interior luminal surface defining the lumen (Figure 1). Note the substrate **is not defined as being limited** to only one layer or one type of material. Therefore, the **substrate in its broadest reasonable interpretation could include** a two-layered material. Michal et al teach a medical device **formed of a substrate formed of the combination of a metal device (col.5, 1.42-44) containing a base coat over top of the metal device.** Therefore, the base coat and metal device combined teach the substrate as claimed in Applicant's claim 37. The base coat comprises a binding component, which is formed of a isocyanate compound (col.8, 1.14-31), such as the urethane-acrylate taught in example 4 in column 16, lines 49-51). **Thus, the substrate comprises copolymers of polyurethane.** A plurality of monomer molecules are directly graft polymerized on at least one of the surfaces of the substrate, forming a top coat thereon (col.11, 1.5-10). The top coat is a polymer or copolymer or a derivative of said polymer or copolymer formed from a monomer or derivative thereof selected from the group consisting of an acrylamide, N,N-dimethylacrylamide, and mixtures thereof (col.8, 1.1-6). [Office Action of August 31, 2006, paragraph 7.]

While the PTO relies upon the figure as an anticipation, it is clear that the literal terms used by the PTO, to rely upon the Michal Figure, are inconsistent with the Michal description at column 2 lines 5 et seq. The Examiner's interpretation of the Michal Figure does not find an enablement in the Michal disclosure at column 2. The word "could" in the first sentence of the USPTO reasoning, ***excerpted above,*** supports the view that the grounds of rejection based on Michal is speculation. Speculation does not constitute written description and does not satisfy

the statutory meaning of 'described', In re Wiggins, 488 F.2d, 179 USPQ 421 (CCPA 1973); In re Arkley, 172 USPQ 524 (CCPA 19720). Accordingly, there is no support for a rejection of claims 37, 44 and 51 over the Michal Figure.

The following excerpts are taken from certain of the cites to Michal in the Office Action(s) and are discussed in connection with Claims 37, 44 and 51. In applicants' view, none of the actual text relied upon by Examiner satisfies the MPEP requirements of an anticipatory reference. Please see MPEP Section 2131: It requires a one to one correspondence of claim elements to those of a prior allegedly anticipatory device.

The Patent Office has relied upon the description at Michal Example 4 [column 16, of Michal]. The description at Example 4 [column 16] describes a stent coated with a urethane-acrylate, applied by dip coating [column 16 line 58] and subsequently applying a top coat of 1.0% peptide, such as albumin as a " top coat solution" [column 16 line 64]. That section does not comport with the requirements of an anticipatory reference with respect to Claim 37. Please see MPEP Section 2131: It requires a one to one correspondence of claim elements to those of a prior allegedly anticipatory device.

The Patent Office also relies upon the Michal description at column 8 line 1-6. The Michal description at column 8 lines 1-6 [sentences in a paragraph bridging column 7 and column 8] recites

> In another embodiment, the binding component...Exemplary of the hydrophilic agent are a (co)monomer selected from.....and N-(3-aminopropyl)methacrylamide; or a polymer of at least one of said (co)monomers co-polymerized with hydropyile monomers, ...from the group consisting of acrylamide, di-methyl acrylamide and N-vinyl pyrrolidone or a peptide

The Patent Office also relies upon the Michal description at column 8 line 14. The Michal description at column 8 recites

> In another embodiment, the binding component is an isocyanate compound and the top coat is a compound containing hydroxyl or amine groups. [Column 8 lines 14 et seq.]

The Examiner further alleges: The linking agent comprises a monomer or derivative selected from acrylamide or N,N-dimethylacrylamide (col.9, 1.46-56). Review of the reference reveals that it states at column 9 line 46 et seq.

> Primary amine groups, hydroxyl, thiol, or carboxy..canbe added to liposome or microsponge linking agents ...For example, compounds having the desired functional groups, such as monomers such as hydroxyethylmehacrylate having a hydroxyl functional group and n-(3-aminopropyl)acrylamide having an amine functional group, can be introduced into the bead composition during synthesis of the microsponges....the process used for functionalizing the microsponges with hydrophilic monomers such as...n-(3-aminopropyl) methacrylamide hydrochloride...

The Examiner also relies upon column 5 lines 34-41 , that portion of the references recites

> The coating can be applied to any device having a polymeric surface..or a metal device..for example, the catheter components may be formed of high density polyethylene, polyethylene terephthalate, and polyolefinic ionomers...

That portion of Michal also fails to anticipate Claim 37; applicants rely on the MPEP Section 2131 for the requirements of an anticipatory reference.

The Examiner further relies upon Column 11 lines 5-10 of Michal which speaks to the ..." a ... coat... on the surface of the coating available to graft the agent of the top coat." In order to anticipate the reference must describe each and every element of the claim. MPEP Section 2131. Michal does not describe each an every element of e.g. Claim 37, 44, 51 and thus does not describe those same elements which are incorporated into claims dependent from claims 37, 44 and 51.

With respect to dependent claims the PTO alleges:

> Regarding claims 38-39, the medical device is a catheter, guide wire or medical instrument (col.2, 1.10-12), and the catheter is specifically a PTCA catheter (col.5, 1.53-56).
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> Regarding claims 40 and 42, the coating further comprises a linking agent that is placed between the substrate including the base coat and the therapeutic containing layer (col.2, 1.62-64). In this embodiment the linking agent is the plurality of monomer molecules and the therapeutic containing layer is the additional layer. Therefore, the coating represented by the linking agent layer of Michal et al serves as a tie coat to adhere the additional layer and has functional groups to attach or bind physiologically or pharmacologically active gents.
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> Regarding claim 41, the top coat is a hydrophilic agent made of acrylamide or N,N-dimethylacrylamide so inherently absorbs large quantities of water to provide moisture absorption or of lubricity.
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> Regarding claim 43, the coating comprises a drug depot permitting the *delivery of drugs form the graft polymer coating (col.4, 1.10-65).*
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> *Regarding claims 58 and 61, a portion or the entire surface of the interior surface, exterior surface or both of the substrate are coated (col.14, 1.1-20).*
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> *Regarding claims 44 and 51, Michal et al anticipate a medical device comprising a substrate constructed and arranged for insertion into a patient and having at least one lumen, said substrate having an exterior surface and interior luminal surface defining the lumen (Figure 1). The substrate comprises polymers or copolymers of polyolefins or polyamides (col.5, 1.34-41). The substrate has either a coating comprising a base coat and top coat system or a coating comprising a coating comprising a grafting component blended with the hydrophilic agent directly grafted to the substrate (col.11, 1.17-21 and col.12, 1.4-7). In the embodiment in which the coating comprises a base coat and top coat* system, the base coat is a plurality of monomer molecules directly graft polymerized on the surface of the substrate, forming a coating thereon, wherein said coating on said substrate is a polymer or copolymer or a derivative of said polymer or copolymer formed from a monomer or derivative thereof selected from the group consisting of an alkylacrylate such as methacrylate (col.8, 1.28-31 and 1.50-54).
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> Regarding claims 45-46 and 52-53, the medical device is a catheter, guide wire or medical instrument (col.2, 1.10-12), and the catheter is specifically a PTCA catheter (col.5, 1.53-56).
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> Regarding claims 47 and 54, in the embodiment in which the coating is the base coat of the coating system the top coat forms an additional layer and the base coat serves as a tie coat to adhere the additional layer to the substrate.
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> Regarding claims 48 and 55, in the embodiment in which the coating is a hydrophilic coating directly grafted to the substrate, the coating absorbs large quantities of water to provide moisture absorption or of lubricity.
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> Regarding claims 49 and 56, in the embodiment in which the coating is the base coat of the coating system the top coat is a physiologically or

pharmacologically active agent that is bonded to the base coat by the functional groups of the base coat.

Regarding claims 50 and 57, in the embodiment in which the coating is a hydrophilic coating directly grafted to the substrate, the coating comprises drugs for delivery within the body, so the coating is a drug depot.

Regarding claims 59-60 and 62-63, a portion or the entire surface of the interior surface, exterior surface or both of the substrate are coated (col.14, 1.1-20).

Michal does not anticipate the dependent claims as Michal does not provide description, of all of the recitations in claims 37, 44 and 55 which per force of law are incorporated into claims dependent therefrom. Withdrawal of the rejections for anticipation is respectfully solicited.

Reconsideration and an early allowance are respectfully solicited.

Respectfully submitted,

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